# Contents Volume 23, 1989

Volume 23, Number 1

1989

#### CONTENTS

		CONTENTS
Alick J. Munro	1	Developing Procedure at Clinical Investigation Units
David A. Carlin Peter Palmer	5	Problems, Pitfalls, and Solutions to the Development of an International Clinical Database
Paolo E. Lucchelli Francesco Gianese	11	Planning a Clinical Research Program for Global Use
Dorle Messerer Joerg Hasford	15	Monitoring Multicenter Trials and its Impact on Trial Results
Bruce P. Greenberg Chialing C. Yen Richard C. Accomando	21	Tracking of Clinical Data for an International Environment
Klaus Stern Juergen Lilienthal Wilhelm Sauermann Reinhard Zentgraf	25	Requirements on an Integrated DBMS for Data From Clinical Trials
Gian Marco Leali Patrizia Pugnetti	37	A Protocol-Independent Database for Clinical Studies
Richard A. Boulding	55	Problems of Global Clinical Data Management
Roland Blomer	65	Practical Relevance of Relational Database Properties for Clinical Database Management
Christian Benichou Gaby Danan	71	Lack of Definitions of Adverse Drug Reactions
Erika F. Nissman Domenic G. Iezzoni	75	Report on a WHO ART-COSTART Translation Project
Donna K. Jackson Susan Piasecki Frank A. Adornato	81	Regulatory Perspective of Worldwide Marketing Authorization Applications

David M. Cocchetto	87	Issues Regarding Compassionate Treatment With Investigational New Drugs
Jay H. Bauman Robert J. Fuentes	95	Drug Information at Glaxo Inc
Gérard B. Bailly Marc Pierredon Richard Rondel Lucien Steru Elie Szapiro	105	Phase IV and Europe
Steven R. Miola	117	Preparing an Individual Clinical Study Report
Mary Ellen Kitler	123	The Elderly in Clinical Trials: Regulatory Concerns
Eric van der Putten Hilary R. Franklin	139	Quality Control in Phase I-III Cancer Clinical Trials
Klaus Abt Iain T. R. Cockburn Albert Guelich P. Krupp	143	Evaluation of Adverse Drug Reactions by Means of the Life Table Method
Roger P. Nelson	151	Organization of Information Departments in the US Pharmaceutical Industry
Bams Abila	165	Efforts to Monitor Adverse Drug Reactions in Africa: A Case Study of Nigeria
	I	Software Survey Section

Volume 23, Number 2

1989

#### **CONTENTS**

## Computer-based Systems for Storage, Reporting, and Analysis of Worldwide Postmarketing Drug Safety Data

- Harry A. Guess 169 Worldwide Drug Safety Information Processing What's Ahead?
- Linda Hostelley 171 Reporting and Tracking Spontaneous Adverse Experience Reports via a Computer Database
- Fred Schneiweiss 179 Capture and Analysis of Spontaneous Adverse Event Data at A. H. Robins

Win M. Castle	183	The ICI Approach: Possible Adverse Reaction Information System
John C. C. Talbot	189	Database Management and Reporting Systems – Foreign-based Companies: The Glaxo Approach
Hugh H. Tilson	197	Discussion Panel: Database Management and Reporting Systems of Foreign-based Companies
Lorely J. E. Maskell	203	Wellcome Group Computer-based System for Worldwide Adverse Drug Reaction Report Management
Judith M. Sills	211	World Health Organization Adverse Reaction Terminology Dictionary
Terry L. Gillum	217	The Merck Regulatory Dictionary: A Pragmatically Developed Drug Effects Vocabulary
Charles Anello	221	Electronic Submission of Periodic Reports
James C. Mannion	225	Turning Computer Reports Into Labeling Changes
Harry A. Guess	231	Discussion Panel: What Can Validly be Done with Spontaneous Adverse Drug Experience Reports?
	Add	litional Articles
H. C. Faulkner III R. H. Farmen	245	Database Design and Management in a Pharmacokinetic Department
L. Edward Kirk G. Edward Collins Michael C. Joseph Deborah Katz	257	Retrovir® (zidovudine): A Unique Drug Information Challenge
Steven J. Blumenthal	267	Discovery of the New Drug Therapies Based on the Study of Adverse Reactions
		Study of Adverse Reactions
Martha M. Rumore Jack M. Rosenberg	273	Comparison of Drug Information Practice in Hospitals and Industry
	273 285	Comparison of Drug Information Practice in
Jack M. Rosenberg  Alan M. Daly Ronald A. Martin Edward J. McGuire		Comparison of Drug Information Practice in Hospitals and Industry  A Microcomputer-based Data Acquisition and Reporting System for Clinical Pathology Data from

Marie A. Abate Arthur I. Jacknowitz James M. Shumway	309	Information Sources Utilized by Private Practice and University Physicians
Jacqueline Anne Sayers Paul Blake	321	An Alternative Approach to Clinical Research Associate Training
Ingrida S. Sketris Anne Bishop Emily Somers G. Ross Baker	327	Developing a Quality Assurance Program for Drug Information Requests Answered by Staff Pharmacists
Bams Abila	335	Drug Discovery: Need to Explore African Phytoresources
Elisabeth Poy John Donahue	339	Quality Assurance of Clinical Trials and Good Clinical Practices in France
	I	Software Survey Section: Entrypoint 90

Volume 23, Number 3

Roger W. Croswell 379

1989

**CONTENTS** Roger W. Croswell 345 Guest Editor's Note 347 Preface Welcome and Introduction Roger W. Croswell 349 Alastair G. Ramsay Session 1: A Brief Overview of the Similarities and Roger W. Croswell 353 Differences between the US and EEC Chemical and Pharmaceutical Requirements for Clinical Trials and for the Marketing Authorization/NDA Anthony S. Angiuoli 355 Comparative Requirements for Initiating Clinical Trials (Including IND and CTC) Roger W. Croswell 365 Questions and Answers: Session 1 371 An Overview and Comparison of the US and EEC Kevin McKenna Chemical and Pharmaceutical Requirements for the Marketing Authorization/New Drug Application

**Initiation of Working Groups** 

Charles S. Kumkumian	391	Session 2: Detailed Review of US and EEC Documentation Requirements for the Active Constituent
Charles S. Kumkumian	393	Requirements for the Active Constituent and Available Guidelines
George R. Wellman	395	The Active Constituent: US and EEC Requirements for Documenting the Method of Preparation, Control of Starting Materials and Intermediates, Control of the Final Bulk Product, and Batch Analyses (Including Those from Toxicology and Clinical Studies) to Support Proposed Impurity Limits
Charles S. Kumkumian	405	The Reference Standard: US and EEC Requirements for Documenting the Proof of Structure and Physical/Chemical Properties
M. O'Brien	411	US and EEC Requirements for Documenting the Stability of the Active Constituent
Richard Margerison	417	Recommendations for a Truly International Registration Dossier
Charles S. Kumkumian	421	Questions and Answers: Session 2
Anthony C. Cartwright	427	Session 3: A Detailed Review of US and EEC Documentation Requirements for the Final Dosage Form and Available Guidelines
Klaus Salm Arnold Urdang	429	The Dosage Form: US and EEC Requirements for Documenting the Method of Preparation and Control of Clinical Trials' Supplies and the Final Dosage Form Proposed for Marketing
Anthony C. Cartwright	439	Comments
G. R. Dukes C. H. Bibart	441	The Dosage Form – US and EEC Requirements for Documenting Its Stability for Clinical Trials and Marketing
Anthony C. Cartwright	449	Questions and Answers: The Dosage Form Stability
J. Michael Morris	453	US and EEC Requirements for Documenting Process and Methods Validation
Karen Hoerlyk	463	The Final Dosage Form: Effectively Dealing with Differences in Local and National Requirements
Anthony C. Cartwright	469	Questions and Answers: Session 3

Yuan-yuan H. Chiu	477	Session 4: Review and Discussion of Special Chemical and Pharmaceutical Requirements in the US for Biotechnology Products
Huib Van de Donk	483	Effectively Dealing with the Special Chemical and Pharmaceutical Considerations in the US and EEC for Biotechnology Products – Part 1A
Birgit Praefke	495	Effectively Dealing with the Special Chemical and Pharmaceutical Considerations in the US and EEC for Biotechnology Products – Part 1B
Alan Dinner John Fose	501	Effectively Dealing with the Special Chemical and Pharmaceutical Considerations in the US and EEC for Biotechnology Products – Part 2
Yuan-yuan H. Chiu	511	Questions and Answers: Session 4
Alastair G. Ramsay	515	Working Group 1: The Active Constituent – A Model International Registration Dossier
Kevin McKenna	529	Working Group 2: The Final Dosage Form – A Model International Registration Dossier
Kevin McKenna	539	Report of the Working Group on "The Finished Dosage Form"
nthony C. Cartwright harles S. Kumkumian Klaus Salm	543	Summary and Closing Remarks: Where to from Here?
Harvey Gurien Gary M. Klee	545	Core Requirements for International Registration of Drugs (New Chemical Entities): Manufacturing and Controls
	561	Workshop Contributors
	I	Software Survey Section: INQUIRE/Text

Volume 23, Number 4

1989

### **CONTENTS**

Promotional and Marketing Activities: Preapproval, Time of Approval, Postapproval

Wayne L. Pines 563 Foreword

Wayne L. Pines 565 A Perspective on Pharmaceutical Marketing

Lloyd Millstein	571	Preparing to Market a New Product
Gail R. Safian	577	Marketing Issues in the Preapproval Stage
Robert C. deGroof	581	Research for a Marketing Plan
William W. Vodra	585	How the FDA Regulates Drug Promotion and Medical Education Before Drug Approval
Kenneth R. Feather	597	Preapproval Promotion: FDA's View
John Chervokas	601	Medical Advertising in the 1990s
Thomas D'Alonzo	605	Co-marketing as an Innovative Marketing Technique
Joseph A. Romano	609	Overview of Current Marketing Issues
Tom Webber	615	The Launch of Xanax
Wendy Borow	619	New Ideas in Medical Education: Medical TV
Kenneth P. Berkowitz	623	Perspectives on Promotional Regulations
David G. Adams	625	FDA Regulation of Promotion of Drugs: A Legal Primer
Louis A. Morris David Banks	635	Current FDA Policies on Drug Promotion
James H. Stewart	641	Marketing to Managed Care Institutions
Wayne I. Roe	647	Reimbursement Planning for New Pharmaceuticals: Strategic Challenges in the 1990s
Sheila Raviv	653	Working with and through Third-party Groups
Charles L. Fry	657	Innovations in Drug Marketing
		Additional Articles
Judi Weissinger	663	Considerations in the Development of Stereoisomeric Drugs: FDA Viewpoint
Wesley Mark Todd	669	Phase I Trials: Past, Present, and Future
R. Vander Stichele M. G. Bogaert	673	Patient Package Inserts: The Belgian Experience with a Mandatory Program
Albert Weissman	679	On the Designation of Race in Clinical Pharmacology Reports

Robert W. Ashworth	687	IND Requirements for Biotechnology Products
George S. Hughes, Jr	693	Challenges in the Design of Phase I and Early Phase II Studies
Beverly M. De Vries George S. Hughes, Jr Steven F. Francom	699	Recruitment of Volunteers for Phase I and Phase II Drug Development Studies
J. S. Mohrland W. J. Bryan	705	Use of Microcomputers to Monitor an Offshore Phase I Clinical Trial
	709	Letters to the Editor
	I	Software Survey Section
	v	Volume 23 Contents and Author Index

